IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Jackson, et al.		
Application No.: 10/828,394		
Filed: 4/19/2004	Group Art Unit:	1635
Title: Method for Treatment of Cancerous Angiogenic Disorders	Examiner:	Tracy Ann Vivlemore
	Confirmation No.:	5855
Attorney Docket No.: UBC.P-033		

REPLY BRIEF FOR APPELLANT

This reply brief is filed in support of Applicants' Appeal from the final rejection mailed 2/28/2006 and in response to the Examiner's Answer mailed October 23, 2006 and supplemented on November 14, 2006.

The Examiner has indicated that the rejections for double-patenting, and the rejection for lack of written description have been withdrawn. Thus, the rejections that remain are those for anticipation.

A common thread running through all of the rejections for anticipation is that some of the diseases said to be treated in the references relied upon are cancers in which angiogenesis may be a factor. Thus, for example, on page 4 of the Examiner's Answer, the argument is made that Monia et al. refer to gliomas as a disease associated with expression of clusterin, and also with angiogenesis as evidenced by the Kunkel reference. As such, it appears that the argument is akin to an inherency argument. Applicants submit that this argument is flawed.

In an anticipation rejection, "it is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (BPAI 1990), citing *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). To establish anticipation under the theory of inherency, "the examiner must provide a basis in fact and/or

technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Levy* at 1464. "Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999).

In the present case, the Kunkel reference establishes that gliomas may exhibit angiogenesis, but the reference does not show that gliomas always exhibit angiogenesis, such that any treatment of a glioma with an anti-clusterin antisense would necessarily result in a reduction in angiogenesis. The same is true of other cancer types identified in the other references. Thus, the standards set in *Levy* and *Robertson* are not met.

In support of the rejection, the Examiner relies on *In re May*, 197 USPQ 601, 607 (CCPA 1978), and *In re Tomlinson*, 150 USPQ 623 (CCPA 1966). Applicants submit that these cases are factually distinguishable from the present case. For example, in *May*, the cited reference taught a compound and its use in providing analgesia, and the claim was directed to a method of providing non-addictive analgesia. Non-addictive analgesia is still analgesia, and thus anticipation was found because the discovery of non-addictiveness of the compound of the art was not a new use. In contrast, in the present case, the references disclose treatment of cancer by inhibition of clusterin, and this is shown to occur in cell culture where angiogenesis is not an issue. The claims are directed to a method of reducing angiogenesis. Thus, the present claims **are** directed to a new use, and not merely to a property of the prior use.

In the case of *Tomlinson*, a claim to a method for achieving stabilization to light exposure by mixing two components was found to be anticipated by a prior disclosure of achieving stabilization against heat exposure by mixing the same two components. The *Tomlinson* Court disregarded the preamble reference to stabilization against exposure to light on the grounds that this stated the result achieved by mixing two materials. The present claims are different. In *Tomlinson*, the components added to the mixture were the same regardless of the intent of the process. In this case, however, the patient treated need not be the same since treatment to reduce

angiogenesis is only an issue at some times and for some patients. Thus, the claims are a new use, and the case law previously cited concerning preamble limitations should be controlling.

The Examiner has acknowledged that the ability of antisense targeted to clusterin was not recognized by the prior art. The Examiner argues, however, that "the prior art teaches administration of the same composition to the same population as encompassed by the instant claims." (Examiner's Answer, Pages 14-15). Applicants submit, however, that the Examiner has not established that the populations treated in the references and those treated in the present invention are necessarily the same. Accordingly, the rejection for anticipation should be reversed.

Respectfully submitted,

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